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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/533,341	03/23/2000	Anna P. Catania	252/029	9950

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EXAMINER	
PARKIN, JEFFREY S	
ART UNIT	**PAPER NUMBER**
1648	14

DATE MAILED: 08/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/533,341	CATANIA, A., ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *1-12 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13 and 15-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11/12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Response to Amendment

Status of the Claims

1. Acknowledgement is hereby made of receipt and entry of the amendment filed 22 August, 2001, wherein claim 13 was amended and new claims 15-23 submitted. Claims 1-12 and 14 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention. A complete response to the final rejection must include cancellation of non-elected claims or other appropriate action (refer to 37 C.F.R. § 1.144 and M.P.E.P. § 821.01). Claims 13 and 15-23 are currently under examination.

35 U.S.C. § 112, Second Paragraph

2. Amended claim 13 and newly submitted claims 15-23 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims simply stipulate the "use of KPV" or a "KPV composition" which is vague and indefinite since the structural and function characteristics of the product are not clearly set forth. For instance, does claim 13 involve the administration of a tripeptide consisting of the amino acid sequence NH_2-Lys-Pro-Val-COOH? Alternatively, do the claims encompass a larger peptide comprising this sequence? Applicants should clearly and unambiguously identify the salient characteristics of the composition and products being administered.

3. Amended claim 13 and newly submitted claim 15 are further rejected under 35 U.S.C. § 112, second paragraph, as being vague and indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claims are incomplete for omitting essential

positive methods steps, such omission amounting to a gap between the steps (refer to M.P.E.P. § 2173.05(q)). *Ex parte Erlich*, 3 U.S.P.Q.2d 1011 (Bd. Pat. App. & Inter. 1986). The claims fail to contain any positive method steps. Applicants should clearly disclose those steps necessary for performing the claimed methodology.

35 U.S.C. § 103(a)

4. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103© and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

6. The criteria that are applied for establishing a background for

determining obviousness under 35 U.S.C. § 103(a) are set forth in *Graham et al. v. John Deere Company of Kansas City et al.; Calmar, Inc. v. Cook Chemical Company; Colgate-Palmolive Company v. Same*, 148 U.S.P.Q. 459 (U.S. Sup. Ct. 1966). These factual inquiries can be summarized as follows: 1) Determining the scope and contents of the prior art. 2) Ascertaining the differences between the prior art and the claims at issue. 3) Resolving the level of ordinary skill in the pertinent art. 4) Considering objective evidence present in the application indicating obviousness or unobviousness (i.e., commercial success, long felt but unsolved needs, failure of others, etc.).

7. Amended claim 13 and newly submitted claims 15-23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lipton (1992). As previously set forth, Lipton teaches that tripeptides bearing the amino acid sequence KPV are efficient **antipyretic** or anti-inflammatory compounds (see Abstract). The inventors reported (see col. 1, lines 19-24) that "This invention relates to a new pharmaceutical composition useful for the treatment of pyrexia and inflammation. More particularly, this invention relates to a tripeptide sequence contained in alpha-Melanocyte Stimulating Hormone and ACTH which has been identified as an antipyretic and anti-inflammatory agent." It was further reported (see col. 2, lines 11-23) that "Studies comparing the antipyretic activity of centrally-administered alpha MSH to the widely-used antipyretic, acetaminophen indicate that alpha MSH is much more potent in reducing fever than acetaminophen, and that alpha MSH was more than 2500 times more potent by weight than acetaminophen in reducing fever." The authors also stated (col. 2, lines 25-35) that "the shorter alpha MSH molecule, which is derived from ACTH, does not stimulate steroid release and there appears to be no irreversible deleterious effects when given to rabbits or man." The inventors

continue in the same column and emphasize that the invention is directed toward amino acids 11-13 of the peptide which consists of Lys-Pro-Val, or KPV. The inventors again note (see col. 2, lines 49-60) that "The present invention provides a pharmaceutical composition useful in the treatment of pyrexia and inflammation." Various well-known pharmaceutical formulations are described including compositions comprising buffers, diluents, stabilizers, and carriers (see col. 6, first and second paragraphs). Appropriate dosages are also provided, as well as, routes of administration. The only limitation of this reference is that it does not disclose the administration of this compound to HIV-infected patients. However, as previously set forth, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to treat HIV-infected patients suffering from secondary infections with the compounds of Lipton (1992), since this would reduce the fever and swelling associated with such opportunistic infections.

Applicants traverse and submit that no such motivation exists in the prior art to administer KPV-containing pharmaceutical compositions to HIV-infected patients. This argument is clearly without merit. It is well-known in the prior art that bacterial and viral infections are often associated with pyretic responses. HIV-infected patients suffer from recurring bouts of secondary infections with a number of bacterial, viral, and fungal microorganisms. These infections often result in pyretic responses. Therefore, there is more than sufficient motivation to administer these peptides to HIV-infected individuals particularly in light of the tremendous antipyretic properties of KPV containing compositions. Applicants further argue that Lipton ('023) fails to describe the anti-microbial/infection properties of KPV containing compounds. Applicants are reminded that no such claim limitation is present. The claims simply stipulate a method for treating secondary infections in HIV-infected individuals. There is no

requirement that the compounds be antimicrobial in nature. Thus, if an HIV-infected patient is suffering from a fever due to a bacterial infection, there is sufficient motivation and a reasonable expectation of success in the prior art that administration of a KPV-containing compound will reduce the fever thereby ameliorating one of the symptoms associated with the secondary infection. This clearly meets all of the claimed limitations pertaining to the treatment of secondary infections. Applicants additionally argue that the anti-inflammatory properties, as they relate to hydrocortisone, would preclude the administration of this compound to HIV-infected patients, presumably because hydrocortisone suppresses the immune system. Applicants appear to have ignored the inventor's statement (col. 2, second paragraph) that "the shorter alpha MSH molecule, which is derived from ACTH, does not stimulate steroid release and there appears to be no irreversible deleterious effects when given to rabbits or to man." Moreover, while KPV-containing compounds and hydrocortisone may share some common properties, nevertheless, they are structurally and functionally different compounds that exert their effects through different pathways and mediators. Moreover, it has been well-documented in HIV infection that proinflammatory cytokines contribute to disease progression by keeping the immune system in an activated state. Thus, one of ordinary skill in the art would have been motivated to administer KPV-containing compositions to HIV-infected patients to treat both the fever, and hyperactive immune state, of HIV-infected patients.

Finality of Office Action

8. Applicant's amendment necessitated any and all new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). **A SHORTENED STATUTORY PERIOD**

FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Correspondence

9. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

10. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

James C. Housel 8/26/02
JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

22 August, 2002